

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)
THIS DOCUMENT RELATES TO ALL CASES	

**CERTIFICATION OF ADAM M. SLATER
IN SUPPORT OF PLAINTIFFS' MOTIONS IN LIMINE**

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' motions in limine.

2. Attached hereto as **Exhibit 1** is a true and accurate copy of the ICH's Draft Consensus Guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (M7).

3. Attached hereto as **Exhibit 2** is a true and accurate copy of the FDA's Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products.

4. Attached hereto as **Exhibit 3** is a true and accurate copy of the transcript of Jun Du's May 28, 2021 deposition.

5. Attached hereto as **Exhibit 4** is a true and accurate copy of the transcript of Eric Gu's April 6, 2021 deposition.

6. Attached hereto as **Exhibit 5** is a true and accurate copy of the transcript of Min Li's April 21, 2021 deposition.

7. Attached hereto as **Exhibit 6** is a true and accurate copy of ZHP01344159, the FDA's November 29, 2018 Warning Letter.

8. Attached hereto as **Exhibit 7** is a true and accurate copy of *FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues* (Jan. 25, 2019).

9. Attached hereto as **Exhibit 8** is a true and accurate copy of USP's General Notices and Requirements.

10. Attached hereto as **Exhibit 9** is a true and accurate copy of USP Pharmacists' Pharmacopeia on USP's General Notices and Requirements.

11. Attached hereto as **Exhibit 10** is a true and accurate copy of USP's <1086> Impurities in Drug Substances and Drug Products.

12. Attached hereto as **Exhibit 11** is a true and accurate copy of ZHP01447235, ZHP's SOP on Genotoxic Impurity Evaluation.

13. Attached hereto as **Exhibit 12** is a true and accurate copy of the transcript of Peng Dong's March 29, 2021 deposition.

14. Attached hereto as **Exhibit 13** is a true and accurate copy of TORRENT-MDL2875-00072713, an internal Torrent email discussing the FDA's finding that its products were adulterated.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of ZHP00061080, the FDA's November 29, 2018 Warning Letter.

16. Attached hereto as **Exhibit 15** is a true and accurate copy of the EMEA's Guideline on the Limits of Genotoxic Impurities.

17. Attached hereto as **Exhibit 16** is a true and accurate copy of HUAHAI-US00007752, the ZnCl₂ DMF.

18. Attached hereto as **Exhibit 17** is a true and accurate copy of PRINSTON00080011, the TEA with sodium nitrite quenching DMF.

19. Attached hereto as **Exhibit 18** is a true and accurate copy of *FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity* (July 13, 2018).

20. Attached hereto as **Exhibit 19** is a true and accurate copy of Amended Expert Report of Ali Afnan, Ph.D., dated January 11, 2023.

21. Attached hereto as **Exhibit 20** is a true and accurate copy of the relevant excerpts of IARC, *Some N-Nitroso Compounds* (1978).

22. Attached hereto as **Exhibit 21** is a true and accurate copy of the relevant excerpts of IARC, *Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42* (1987).

23. Attached hereto as **Exhibit 22** is a true and accurate copy of the abstract for ZHP's Patent for the method for Synthesizing Valsartan (W02020010643), dated July 17, 2018.

24. Attached hereto as **Exhibit 23** is a true and accurate copy of the transcript of Jucai Ge's May 27, 2022 deposition

25. Attached hereto as **Exhibit 24** is a true and accurate copy of the transcript of Min Li's April 20, 2021 deposition.

26. Attached hereto as **Exhibit 25** is a true and accurate copy of the transcript of Jun Du's May 27, 2021 deposition.

27. Attached hereto as **Exhibit 26** is a true and accurate copy of the transcript of Hai Wang's March 10, 2021 deposition.

28. Attached hereto as **Exhibit 27** is a true and accurate copy of ZHP01451842, Princeton's valsartan ANDA, Section 2.3.S Drug Substance.

29. Attached hereto as **Exhibit 28** is a true and accurate copy of PRINBURY00058078, Princeton's valsartan ANDA, Section 3.2.P.5.5 Characterization of Impurities.

30. Attached hereto as **Exhibit 29** is a true and accurate copy of PRINBURY00058083, Princeton's valsartan ANDA, Section 3.2.P.5.6 Justification of Specification.

31. Attached hereto as **Exhibit 30** is a true and accurate copy of PRINSTON00037968, Princeton's valsartan HCTZ ANDA, Section 2.3.S Drug Substance-Valsartan.

32. Attached hereto as **Exhibit 31** is a true and accurate copy of PRINSTON00183155, Princeton's valsartan HCTZ ANDA, Section Characterization of Impurities.

33. Attached hereto as **Exhibit 32** is a true and accurate copy of PRINSTON0017767 , Princeton's valsartan HCTZ ANDA, Section 3.2.P.5.6 Justification of Specifications.

34. Attached hereto as **Exhibit 33** is a true and accurate copy of ZHP01303141, Valsartan USP Monograph.

35. Attached hereto as **Exhibit 34** is a true and accurate copy of ZHP02614594, Valsartan Tablets USP Monograph.

36. Attached hereto as **Exhibit 35** is a true and accurate copy of PRINSTON00141349, Valsartan HCTZ USP Monograph.

37. Attached hereto as **Exhibit 36** is a true and accurate copy of Liteplo, Meek, and Windle, *N-Nitrosodimethylamine: Concise International Chemical Assessment Document 38* (WHO 2002).

38. Attached hereto as **Exhibit 37** is a true and accurate copy of the relevant portion of ZHP02563814, Annex 1a.1 NDMA and NDEA Test Results for all ARBs in USDMF Grade, namely the valsartan test results.

39. Attached hereto as **Exhibit 38** is a true and accurate copy of ZHP02563015, an email from ZHP to the FDA attaching ZHP02563814.

40. Attached hereto as **Exhibit 39** is a true and accurate copy of PRINSTON00158423, ZHP's response to the FDA's requests for additional information related to the November 29, 2018 Warning Letter.

41. Attached hereto as **Exhibit 40** is a true and accurate copy of PRINSTON00162349, the FDA's EIR for the July 23 to August 3, 2018 inspection.

42. Attached hereto as **Exhibit 41** is a true and accurate copy of ZHP00079913, ZHP's Response to DMF Information Request Letter.

43. Attached hereto as **Exhibit 42** is a true and accurate copy of TORRENT-MDL2875-00133890, Torrent's Valsartan Impact Assessment of NDEA.

44. Attached hereto as **Exhibit 43** is a true and accurate copy of Gomm W, Röthlein C, Schüssel K, Brückner G, Schröder H, Heß S, Frötschl R, Broich K, Haenisch B. *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of*

Cancer—A Longitudinal Cohort Study Based on German Health Insurance Data.

Dtsch Arztebl Int. 2021 May 28;118(21):357-362. doi: 10.3238/arztebl.m2021.0129.

PMID: 34247699; PMCID: PMC8372009.

45. Attached hereto as **Exhibit 44** is a true and accurate copy of the relevant portion of the transcript of Tiffanie Mrakovich's August 31, 2021 deposition.

46. Attached hereto as **Exhibit 45** is a true and accurate copy of a letter from CMS to Summacare, dated August 11, 2014.

47. Attached hereto as **Exhibit 46** is a true and accurate copy of the transcript of Jucai Ge's May 26, 2022 deposition.

48. Attached hereto as **Exhibit 47** is a true and accurate copy of ZHP's translation of ZHP00190573, the July 27, 2017 email.

49. Attached hereto as **Exhibit 48** is a true and accurate copy of ZHP's Stipulation, dated May 13, 2022.

50. Attached hereto as **Exhibit 49** is a true and accurate copy of SOLCO00024231, Solco's recall notice.

51. Attached hereto as **Exhibit 50** is a true and accurate copy of SOLCO00024226, Princeton's recall notice.

52. Attached hereto as **Exhibit 51** is a true and accurate copy of the transcript of Min Li's April 22, 2021 deposition.

53. Attached hereto as **Exhibit 52** is a true and accurate copy of Health Canada's *Impurities found in certain angiotensin II receptor blocker (ARB) products, also known as sartans* (Apr. 29, 2019), <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/angiotensin-receptor-blocker.html>.

54. Attached hereto as **Exhibit 53** is a true and accurate copy of the FDA's December 5, 2022 Letter to Valisure, LLC.

55. Attached hereto as **Exhibit 54** is a true and accurate copy of ZHP00662283.

56. Attached hereto as **Exhibit 55** is a true and accurate copy of the relevant portion of the transcript of Dawn Chitty's May 13, 2021 deposition.

57. Attached hereto as **Exhibit 56** is a true and accurate copy of the relevant portion of the transcript of Sushil Jaiswal's June 4, 2021 deposition.

58. Attached hereto as **Exhibit 57** is a true and accurate copy of the relevant portion of the transcript of Daniel Barreto's April 14, 2021 deposition.

59. Attached hereto as **Exhibit 58** is a true and accurate copy of the relevant portion of the transcript of Claire Lyon's April 27, 2021 deposition.

60. Attached hereto as **Exhibit 59** is a true and accurate copy of the relevant portion of the transcript of Roger William's February 17, 2022 deposition.

61. Attached hereto as **Exhibit 60** is a true and accurate copy of the relevant portion of the transcript of Raphael Nudelman's April 8, 2021 deposition.

62. Attached hereto as **Exhibit 61** is a true and accurate copy of the transcript of the opening arguments in *Sugarman v. Johnson & Johnson*.

63. Attached hereto as **Exhibit 62** is a true and accurate copy of TORRENT-MDL2875-00000003, Torrent's valsartan ANDA.

64. Attached hereto as **Exhibit 63** is a true and accurate copy of TORRENT-MDL2875-00002771, Torrent's valsartan HCTZ ANDA.

65. Attached hereto as **Exhibit 64** is a true and accurate copy of TORRENT-MDL2875-00019489, Torrent's valsartan amlodipine HCTZ ANDA.

66. Attached hereto as **Exhibit 65** is a true and accurate copy of TEVA-MDL2875-00680841, ZHP's memo to customers regarding the NDMA contamination.

67. Attached hereto as **Exhibit 66** is a true and accurate copy of the relevant portion of the transcript of Daniel Barreto's April 15, 2021 deposition.

68. Attached hereto as **Exhibit 67** is a true and accurate copy of TEVA-MDL2875-00042637, TEVA's Valsartan Testing Strategy, dated August 14, 2018.

69. Attached hereto as **Exhibit 68** is a true and accurate copy of the relevant portion of the transcript of Dr. Rena Conti's February 1, 2024 deposition.

70. Attached hereto as **Exhibit 69** is a true and accurate copy of the relevant portion of the transcript of Andrew Colby's February 7, 2024 deposition.

71. Attached hereto as **Exhibit 70** is a true and accurate copy of the relevant portion of the transcript of Jorge Lopez's April 29, 2021 deposition.

MAZIE SLATER KATZ & FREEMAN, LLC

Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: February 16, 2024